

Applicant : Robert Thomas Hudak
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Attorney's Docket No.: (40002-0271)
17072-002001

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

What is claimed:

1. (amended) A specimen collection device, comprising:
 - (a) a chamber, wherein said chamber ~~is capable of collecting~~ collects a specimen;
 - (b) a reservoir, wherein said reservoir is ~~capable of receiving~~ receives a portion of said specimen from said chamber; further wherein said reservoir is capable of receiving a test device;
 - (c) a valve functionally interposed between said chamber and said reservoir ~~is capable of transferring~~ , wherein said valve is actuated to transfer at least a portion of said specimen from said chamber to said reservoir such that said chamber and said reservoir are not in direct fluid communication and wherein said valve can be actuated only once.
2. (original) The specimen collection device of claim 1, wherein said chamber comprises a seal.
3. (original) The specimen collection device of claim 2, wherein said seal is a tamper resistant seal or tamper evident seal.

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4. (original) The specimen collection device of claim 2, wherein said seal is a screw-lid or a snap-lid.

5. (original) The specimen collection device of claim 2, wherein said seal is leak resistant.

6. (original) The specimen collection device of claim 2, wherein said seal comprises at least one O-ring.

7. (amended) The specimen collection device of claim 2, wherein said seal is leak resistant to at least about 0 ~~PSI~~ pounds per square inch to at least about 50 ~~PSI~~ pounds per square inch internal pressure.

8. (amended) The specimen collection device of claim 1, wherein said chamber ~~can hold~~ holds a specimen between about 0.0001 milliliter and about 1,000 milliliters.

9. (original) The specimen collection device of claim 1, wherein said chamber further comprises a temperature sensing device.

10. (original) The specimen collection device of claim 1, wherein said chamber comprises at least one label on surface on which to record data pertaining to said specimen.

11. (original) The specimen collection device of claim 1, wherein said chamber comprises metal, silicon, glass, ceramic, plastic or a polymer.

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12. (original) The specimen collection device of claim 1, wherein said chamber is tapered.

13. (amended) The specimen collection device of claim 1, wherein said chamber optionally comprises a ~~substantially~~ planar surface.

14. (original) The specimen collection device of claim 1, wherein said reservoir comprises metal, silicon, glass, ceramic, plastic or a polymer.

15. (original) The specimen collection device of claim 1, wherein said reservoir snugly engages said test device.

16. (original) The specimen collection device of claim 1, wherein said specimen is a liquid specimen.

17. (original) The specimen collection device of claim 1, wherein said specimen is a biological specimen.

18. (original) The specimen collection device of claim 1, wherein said specimen has a volume between about 0.0001 milliliter and about 1,000 milliliters.

19. (original) The specimen collection device of claim 1, wherein said specimen is urine, blood or serum.

20. (amended) The specimen collection device of claim 1, wherein said valve is ~~substantially~~ cylindrical.

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21. (original) The specimen collection device of claim 1, wherein said valve comprises a piston configuration.

22. (original) The specimen collection device of claim 1, wherein said valve is unidirectional.

23. (original) The specimen collection device of claim 1, wherein said valve cannot be actuated more than once.

24. (original) The specimen collection device of claim 1, wherein said valve comprises a seal.

25. (original) The specimen collection device of claim 1, wherein said valve comprises at least one O-ring.

26. (original) The specimen collection device of claim 1, wherein said valve is leak resistant between said chamber and said reservoir.

27. (original) The specimen collection device of claim 1, wherein said valve is leak resistant between said chamber and said reservoir to at least about 0 PSI to at least about 50 PSI pressure on said chamber.

28. (original) The specimen collection device of claim 1, wherein said valve comprises metal, silicon, glass, ceramic, plastic or a polymer.

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29. (amended) The specimen collection device of claim 1, wherein said chamber ~~and said reservoir comprises a single unit~~ is integrally attached to said reservoir.

30. (amended) The specimen collection device of claim 1, wherein said chamber ~~and said reservoir comprises separate units~~ is removably attached to said reservoir.

31. (original) The specimen collection device of claim 1, wherein said reservoir is attached to said chamber.

32. (original) The specimen collection device of claim 1, wherein said reservoir is removable from said chamber.

33. (original) The specimen collection device of claim 1, further comprising at least one test device.

34. (original) The specimen collection device of claim 1, wherein said test device comprises at least one test strip.

35. (original) The specimen collection device of claim 34, wherein said test strip is capable of performing at least one specific binding reaction.

36. (original) The specimen collection device of claim 35, wherein said specific binding reaction comprises an immunoassay.

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37. (original) The specimen collection device of claim 34, wherein said test strip is capable of performing an enzymatic reaction.

38. (original) The specimen collection device of claim 34, wherein said test strip is capable of performing a chemical reaction.

39. (original) The specimen collection device of claim 1, wherein said test device is capable of detecting at least one analyte of interest.

40. (original) The specimen collection device of claim 39, wherein said analyte of interest is selected from the group consisting of a drug, a drug of abuse, a hormone, a protein, a nucleic acid molecule, an etiological agent and a specific binding member.

41. (original) The specimen collection device of claim 1, wherein said test device further comprises a wick.

42. (original) The specimen collection device of claim 1, wherein said test device can be separate from said specimen collection device.

43. (original) The specimen collection device of claim 1, wherein said chamber, said valve, said reservoir or said test device comprises an adulteration determination device.

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44. (amended) A method of detecting an analyte of interest in a specimen, comprising:

- 1- a) providing the specimen collection device of claim 1;
- 2- b) providing a specimen into said chamber;
- 3- c) actuating said valve to transfer at least a portion of said specimen from said chamber to said reservoir; and
- 4- d) contacting the transferred portion of said specimen with a test device to detect an analyte of interest, ~~wherein said specimen is optionally within said reservoir.~~

45. (original) The method of claim 44, wherein said specimen is a biological specimen.

46. (original) The method of claim 44, wherein said specimen is provided directly or indirectly from a test subject into said chamber.

47. (original) The method of claim 44, wherein after providing said specimen into said chamber, said chamber is sealed with a tamper resistant or tamper evident seal.

48. (original) The method of claim 47, wherein after the step of providing a specimen into said chamber a temperature sensing device can be examined.

49. (original) The method of claim 44, wherein said portion of said specimen enters into said valve.

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50. (original) The method of claim 44, wherein said portion of said specimen is at least about one milliliter.

51. (original) The method of claim 44, wherein said valve is actuated such that said portion of said specimen is transferred away from said chamber and delivered into said reservoir.

52. (original) The method of claim 51, wherein actuation of said valve is unidirectional.

53. (original) The method of claim 51, wherein said transfer of said portion of said specimen into said reservoir is irreversible.

54. (original) The method of claim 51, wherein said chamber and said reservoir are not in direct fluid communication.

55. (original) The method of claim 44, wherein said test device is an immunoassay test device.

56. (original) The method of claim 55, wherein said immunoassay test device comprises one or more lateral flow test strips.

57. (original) The method of claim 44, wherein after the step of providing a specimen to said collection device an adulterant determination device can be examined.

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58. (amended) The method of claim 44, wherein after said chamber containing said specimen has been sealed, the sealed chamber ~~can be transported~~ is transportable to a laboratory facility for confirmation of test results provided by said test device.

59. (amended) The method of claim 44, wherein after said chamber containing said specimen has been sealed, the sealed chamber ~~can be transported~~ is transportable to a laboratory facility for at least one additional test.

60. (new) The specimen collection device of claim 1, wherein the valve includes a handle for actuating the valve, wherein the handle functionally disengages from the valve after the valve is actuated and wherein the valve cannot be actuated with the handle functionally disengaged therefrom.